

DATATRAK uEDC™ Dynamic Forms & Questions **Optimize Your Clinical Trial Data Management**

Data management is a time consuming task; any tools that can streamline the cleaning process will help reduce costs and allow clinical conclusions to be reached more quickly. Ensuring only the pertinent questions are recorded for each patient can streamline not only the data entry process, but also cleaning, analyzing and reporting.

It is critical that all appropriate questions are included on a patient form in the eCRF (electronic case report form) to ensure necessary information is gathered to provide complete and thorough data to support the clinical trial. However questions that are not necessary for all participants drive unnecessary effort, increase the cleaning time and possibility of errors thus adding cost to the trial. Balancing the need to provide a thorough set of relevant questions and managing time and cost investment can be difficult. Dynamic forms and questions create the opportunity for the eCRF to be customized to each patient, based on their profile. Only the applicable questions within forms, or entire forms, will be recorded for the patient.

With dynamic forms and questions in *DATATRAK ONE*® uEDC, questions within forms and entire forms can be configured to apply to a specific subset of patients. Pre-existing conditions, lifestyle questions, and medications are just some of the examples where additional information may be required if the patient answers with a confirmation. If the condition does not apply, additional questions are not required, and thus, not displayed.

Time and Cost Savings

DATATRAK regularly receives feedback from our customers on the benefits they value most in our products; a common theme is time and cost savings. The application of dynamic forms and questions, one of the features of our uEDC product, is often raised.

Time and cost savings from dynamic forms and questions are seen in two key areas:

- Higher Quality Data
- More Efficient Monitoring and Data Review

Higher Quality Data

High quality data is imperative to a successful clinical trial. Quality is generated through ensuring all required data is answered, with excessive information excluded, and minimizing data entry errors.

Dynamic forms and questions record for each patient their specific set of applicable questions. Unnecessary questions are not removed; they never appear. Optimizing the question set ensures insightful content is gathered, creating the very basis of the data required for the trial.

Data entry errors are minimized, as only the pertinent information is entered. No additional comments are required to state if a question or set of questions is not required or applicable. Only the questions that have an impact on the trial are entered.

More Efficient Monitoring and Data Review

As the eCRFs are reviewed, fewer modifications are required as the 'not applicable' questions do not need to be verified for accuracy or modified to include a statement to that effect. Reducing modification of data entered reduces time and cost requirements, and eases review during the source verification process as only applicable forms and questions are shown by patient.

Throughout the clinical trial, patients' status may change. With dynamic forms and questions, only the forms that are required for each segment of the trial are distributed to the patient, making it easy to see patient participation at each level. No more digging through data to determine patient exits; only forms appropriate for the participation are reflected.

As Data Managers review submitted data, there is no need to wonder if a question was simply left blank or not seen. Only applicable forms and questions providing detailed responses are displayed and available for entry, leaving the Data Manager with only pertinent data to reconcile.

DATATRAK solutions deliver time and cost savings throughout the clinical trial. Our unified platform is the foundation of all of our solutions, generating increased efficiency to every trial. *DATATRAK* uEDC offers many benefits for clinical trial data management, including dynamic forms and questions, support for risk-based monitoring, and the state-of-the art intuitive unified interface.